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10/087,014	03/01/2002	Henrik Hansen	12013/59301	2646

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EXAMINER

TSOY, ELENA

ART UNIT	PAPER NUMBER
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1762

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/087,014

Applicant(s)

HANSEN ET AL.

Examiner

Elena Tsoy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18, 19 and 25-39 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-16, 18, 19 and 25-39 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

1. Amendment filed on 5/2/2006 has been entered. Claims 20-24 have been cancelled. New claims 30-39 have been added. Claims 1-16, 18-19, 25-39 are pending in the application.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 29 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the same reasons as set forth in paragraph 4 of the Office Action mailed on 2/8/06 because the amended claim 29 is still directed to a **combination of spraying** therapeutic from the channel positioned in the drum and tumbling an implant **into a vat** of therapeutic, which is, according to P18 of the specification, **alternative** to *spraying* therapeutic.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 2, 12, 13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Vickery (US 3,991,750) in view of Lucke (5,302,201) for the reasons of record as set forth in Paragraph No. 2 of the Office Action mailed on December 3, 2004.
6. Claim 3 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Vickery (US 3,991,750) in view of Lucke (5,302,201), further in view of Yalkowsky (US 4,489,026) for the

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reasons of record as set forth in Paragraph No. 3 of the Office Action mailed on December 3, 2004.

7. Claim 4 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Vickery (US 3,991,750) in view of Lucke (5,302,201), further in view of Forster (US 4,581,242) for the reasons of record as set forth in Paragraph No. 4 of the Office Action mailed on December 3, 2004.

8. Claims 7, and 9-11 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Vickery (US 3,991,750) in view of Lucke (5,302,201), further in view of Dunajtschik (US 4,586,457) for the reasons of record as set forth in Paragraph No. 6 of the Office Action mailed on December 3, 2004.

9. Claim 19 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Vickery (US 3,991,750) in view of Lucke (5,302,201), further in view of Fernandez et al (US 3,696,188) for the reasons of record as set forth in Paragraph No. 7 of the Office Action mailed on December 3, 2004.

10. Rejection of claims 5, 6, 8, 14-16, 18, 25-28 under 35 U.S.C. 103(a) as being unpatentable over Iguchi et al (US 5,756,553) in view of Forster (US 4,581,242) and Schwartz et al (US 6,607,598) has been withdrawn due to amendment.

11. Rejection of claim 29 under 35 U.S.C. 103(a) as being unpatentable over Vickery in view of Lucke, further in view of Sandrock (US 3,484,360) has been withdrawn due to amendment.

12. Claims 5-9, 12-16, 18, 25-28, 32-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roorda et al (US 20040261698) in view of Forster and (applied as evidence) Schwartz et al (US 6,607,598)

Roorda et al disclose a method of coating stents (See P16) for the delivery of therapeutic (See P21) comprising: placing stents into a rotatable pan 204 including a drum, tumbling the stents by rotating the drum about a longitudinal axis of the drum (obviously stents are free to strike the bottom or the wall of the drum) (See Fig. 2; P17), spraying a therapeutic in a solvent carrier over the tumbling stents (See P18); and removing the solvent using hot air of 15-200 °C (drying) (See P19).

Roorda et al fail to teach that the drum has a plurality of orifices in the wall (Claims 5, 12, 13); and the medical implant has a masking material on at least one surface (Claim 5).

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Forster teaches blowing air or gas up through the bed of objects in a side vented coating pan (i.e. having a plurality of orifices in the wall as claimed) allows drying the objects at all levels (i.e. suspending the medical implants) provides defect-free coatings as they are held aloft (See column 1, lines 18-30, 42-50).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided orifices in a rotary pan Roorda et al to blow air up through the stents to suspend the stents with the expectation of providing the desired defect-free coatings, as taught by Forster.

Schwartz et al state that *masking* techniques are known in the art for partial coating of stents to result in coating of predetermined stent segments (See column 11, line 67; column 12, lines 1-2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used known masking techniques for coating stents in Roorda et al with the expectation of providing the desired coating of predetermined segments of the stents.

As to claim 6, Claim 6 is rejected because collection of any fluid inherently requires a reservoir.

As to claims 15, 26, Roorda et al in view of Forster fail to teach that gas is an inert gas.

It is well known in the art that inert gas should be used in case a bioactive coating is sensitive to air.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used inert gas in Iguchi et al in view of Forster with the expectation of providing the desired high quality bioactive coating if a bioactive coating is sensitive to air.

As to claims 16, 28, blowing of air or gas does not continue indefinitely and thus is “periodic”.

As to claims 18, 25, Forster further teaches that coating can be sprayed through a nozzle 12 (See Fig. 4).

13. Claims 1, 30, 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roorda et al in view of Forster and Schwartz et al, further in view of Lucke.

Roorda et al in view of Forster fail to teach that the therapeutic is sprayed by moving it through a channel positioned in the drum and containing a plurality of orifices (Claims 1, 29)

Lucke teaches that coating implants in rotary drums containing a plurality of orifices 51 in the wall, where a pharmaceutical coating material is applied (See column 4, lines 21-22) by moving the coating materials through a carrier (channel) 54 positioned in the drum and having a plurality of spraying nozzles (orifices) 53, spraying the coating materials through the nozzles 53 (See Fig. 4; column 7, lines 30-38) and the applied coating is dried by blowing a gas, allows to achieve high quality of coated cores (See column 4, lines 34-35).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have sprayed a coating material in Roorda et al in view of Forster by moving the coating material through a carrier positioned in the drum and having a plurality of spraying nozzles with the expectation of providing the desired high quality of coatings because Lucke teaches that coating implants in rotary drums containing a plurality of orifices in the wall, where a pharmaceutical coating material is applied by moving the coating materials through a carrier (channel) positioned in the drum and having a plurality of spraying nozzles (orifices), spraying the coating materials through the nozzles and the applied coating is dried by blowing a gas, allows to achieve high quality of coated implants.

14. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roorda et al in view of Forster, further in view of Lucke, and further in view of Sandrock.

Roorda et al, Forster and Lucke are applied here for the same reasons as above. Roorda et al in view of Forster in view of Lucke fail to teach that an implant is tumbled into a *vat* of therapeutic.

Sandrock teaches that articles can be coated in a rotating drum having perforations by partially immersing the drum in a coating liquid so that the perforations admit the coating liquid and tumbling the articles in a drum (See column 3, lines 50-53).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have placed a bottom of a drum of Roorda et al in view of Forster in view of Lucke in a bath so that the drum is partially immersed in a coating liquid sprayed from a channel; and implants are tumbled into a vat of therapeutic formed by spraying and by admitting the therapeutic through the perforations because Sandrock teaches that articles can be coated in a rotating drum having perforations by partially immersing the drum in a coating liquid so that the perforations admit the coating liquid and tumbling the articles in a drum.

Response to Arguments

15. Applicants' arguments filed 5/2/2006 have been fully considered but they are not persuasive.

(A) Applicants argue that prima facie case of obviousness has not been made out because the statement in the Office action that "It would have been obvious to one of skill in the art at the time the invention was made," is conclusory and because it lacks any citation to an objective source showing this purported motivation to combine Lucke and Vickery.

The argument is unconvincing because the Examiner stated clearly the reason to combine Lucke and Vickery thereby providing motivation.

The argument is unconvincing because the Examiner stated clearly the reason to combine Lucke and Vickery thereby providing motivation. Vickery does not limit his teaching to a *particular* rotary drum for coating pellets, and Lucke teaches that coating cores in rotary drums containing a plurality of orifices 51 in the wall, where a pharmaceutical coating material is applied (See column 4, lines 21-22) by moving the coating materials through a carrier (channel) 54 positioned in the drum and having a plurality of spraying nozzles (orifices) 53, spraying the coating materials through the nozzles 53 (See Fig. 4; column 7, lines 30-38) and the applied coating is dried by blowing a gas, allows to achieve high quality of coated cores (See column 4, lines 34-35). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have coated cores of Vickery using a rotary drum of Lucke containing a plurality of orifices, where a pharmaceutical coating material is applied by moving the coating materials through a carrier positioned in the drum and having a plurality of spraying nozzles, and spraying the coating materials through the nozzles, and the applied coating is dried by blowing a gas with the expectation of providing the **desired high quality of coated cores**, as taught by Lucke.

(B) Applicants argue that claim 12 is patentable over the cited references because it recites, "drawing a compressible fluid into the drum." Neither reference discloses or suggests this language.

The argument is unconvincing because *blowing a gas* in cited references involves "drawing a compressible fluid into the drum."

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(C) Applicants argue that claim 13 is patentable over the cited references at least because it recites, "heating the rotatable drum after spraying the therapeutic into the drum."

The argument is unconvincing because Vickery teaches: "During the coating process the spheres used for the inert cores are kept in constant movement so that the drug/carrier solution is uniformly coated on the spheres, then the solvent is removed by evaporation, generally blowing hot air across the spheres while keeping them in constant motion, again to assure uniformity of coating. The spheres are kept in constant motion by employing a coating pan which is constantly and uniformly revolved at a uniform rate or by using an air suspension column in which the spheres are suspended in an air stream. The solvent is applied intermittently along with the hot air in a pre-set spary/dry cycle. " (See column 9, lines 8-15), which clearly reads on "heating the rotatable drum after spraying the therapeutic into the drum."

(D) Applicants argue that claim 4 is patentable over the cited references at least because Lucke pushes gas out of the rotating drum 48 during its operation (see arrows 62 in Fig. 4 of Lucke), so the suggestion of using Forster to modify Lucke by blowing air up through a bed of objects is exactly opposite to the teaching and operation of Lucke, and, thus, is improper and cannot stand.

The argument is unconvincing because one of ordinary skill in the art would have clear motivation to modify Lucke by blowing air up through a bed of objects opposite to the teaching and operation of Lucke because Forster teaches that blowing air or gas up through the bed of objects in a side vented coating pan (i.e. having a plurality of orifices in the wall as claimed) allows drying the objects at all levels (i.e. suspending the medical implants) provides defect-free coatings as they are held aloft (See column 1, lines 18-30, 42-50).

(E) Applicants argue that claims 7 and 9 are patentable over the cited references because cited references show neither "re-circulating the compressible fluid in the drum" nor "heating the compressible fluid in the compressible fluid source prior to forcing the compressible fluid into the drum."

The argument is unconvincing because both limitations are within the level of ordinary engineering skill.

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Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elena Tsoy whose telephone number is 571-272-1429. The examiner can normally be reached on Monday-Thursday, 9:00AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elena Tsoy
Primary Examiner
Art Unit 1762

ELENA TSOY
PRIMARY EXAMINER
E. Tsoy

June 15, 2006